

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

J&J Reference: **DEP5213USNP**

MMB Docket No. 1671-0285

Confirmation No. 2398

In re patent application of: Ondrla et al.

Examiner: Javier G. Blanco

Application No. 10/748,448

Group Art Unit: 3738

Filed: December 30, 2003

Title: Joint Prosthesis with Infinitely Positionable Head

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

April 21, 2008

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James D. Wood

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Signature

April 21, 2008

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LETTER

Sir:

Enclosed is an Appeal Brief in connection with the above-identified patent application. The Notice of Appeal was filed on February 19, 2008, and the Appeal Brief is due two months from this date. Since the due date for filing an Appeal Brief fell on Saturday, April 19, 2008, this Appeal Brief is being timely filed on Monday, April 21, 2008. Also enclosed herewith is a check for \$510.00 to cover the required fee.

Commissioner for Patents April 21, 2008 Page 2 of 2

Additionally, please provide any extensions of time which may be necessary and charge any fees which may be due to Account No. 13-0014, but not to include any payment of issue fees.

Respectfully submitted,

MAGINOT, MOORE & BECK LLP

/James D. Wood/

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J&J Docket No. DEP5213USNP

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Application of: **Ondrla et al.** Group Art Unit: **3738**

Serial No. 10/748,448 Examiner: Javier G. Blanco

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Date of Signature

APPEAL BRIEF

Sir:

This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the rejection of the claims 19-37 of the above-identified patent application. These claims were indicated as finally rejected or withdrawn in an Office Action dated September 18, 2007. The

\$510.00 fee required under 37 CFR § 41.20(b) (2) is submitted herewith. Also, please 04/25/2008 RFEKADUI 00000028 10748448

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provide any extensions of time that may be necessary and charge any fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this patent application (serial no. 10/748,448).

(3) STATUS OF CLAIMS

Claims 19-37 are pending in the application.

Claims 1-18 have been canceled.

Claims 19-37 are rejected.

Claims 27-37 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

The rejection of claims 19-26 is not being appealed.

(4) STATUS OF AMENDMENTS

Appellants have filed no amendments after receipt of the September 18, 2007

Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

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The present invention relates to a prosthetic device with an infinitely variable head. (See, e.g. Appellants' specification at Abstract). In accordance with one non-limiting embodiment, a prosthesis 10 includes a humeral component or stem 12, a humeral head or head component 14 and a conjoining member 30. (See, e.g. Appellants' specification at page 8, lines 19-22 and FIG. 1).

The conjoining member 30 is configured to press-fit to the stem 12 when the conjoining member 30 is in an unlocked state. (See, e.g. Appellants' specification at page 9, lines 28-30). The conjoining member 30 includes a spheroid body 32 which may be slightly less, slightly more or equal to the diameter of a socket 20 in the stem 12. (See, e.g. Appellants' specification at page 9, lines 5-7). The conjoining member 30 further includes a bore 34 which in this embodiment tapers inwardly along the axis of the spheroid body 32. (See, e.g. Appellants' specification at page 10, lines 24-26 and FIG. 1). The conjoining member includes expansion members 40, 41, 42 and 43 which are configured to radially expand when an expander is received within the bore 34. (See, e.g. Appellants' specification at page 11, lines 15-18 and FIG. 3).

The head 14 includes an articulation surface 24 and an expander or neck 28. (See, e.g. Appellants' specification at page 12, lines 5-8 and FIG. 1).

In operation the expander 28 is received within the bore 34 of the conjoining member 30. Initially, the head 14 and the conjoining member 30 are press-fit to the stem 12 to allow for additional modification of the orientation of the components. (See, e.g. Appellants' specification at page 12, lines 12-17). By movement of the expander 28 further into the bore 34, the expander contacts the expansion members 40, 41, 42 and 43

and causes them to be spread outwardly from the axis of the bore 34. (See, e.g. Appellants' specification at page 12, lines 17-22). This causes the expansion members 40, 41, 42 and 43 to press against the cavity 20, locking the expander 28, the conjoining member 30 and the stem 12. (See, e.g. Appellants' specification at page 12, line 23 through page 13, line 11 and FIG. 5).

The additional information required by the United States Patent Office is as follows. Claims 27 and 32 are independent claims.

Claim 27

Claim 27 recites:

A prosthesis comprising (see, e.g., Appellants' specification at Abstract):

a stem configured to be implanted within a bone, the stem defining a first coupler bore (see, e.g., Appellants' specification at page 7, lines 6-10, page 8, lines 18-19 and FIG. 2);

a joint component having a bearing surface and defining a second coupler bore (see, e.g., Appellants' specification at page 6, line 22 through page 7, line 1 and FIG. 2); and

a mounting element having (i) a proximal portion received within the second coupler bore of the joint component in a friction fit manner (see, e.g., Appellants' specification at page 7, lines 1-5 and FIG. 2), and (ii) a spherical articulating portion received within the first coupler bore of the stem (see, e.g., Appellants' specification at page 7, lines 6-10, and FIG. 2),

wherein the stem includes a proximal surface that defines a coupler opening through which the mounting element extends, and the stem, when viewed in a cross-

section, further includes an interior wall portion located within the first coupler bore that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line (see, e.g., Appellants' specification at page 7, lines 6-10, and FIG. 2), and

wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line (see, e.g., Appellants' specification at page 7, lines 6-10, and FIG. 2).

Claim 32

Claim 32 recites:

A prosthesis comprising (see, e.g., Appellants' specification at Abstract):

a stem configured to be implanted within a bone, the stem including an internal bore (see, e.g., Appellants' specification at page 7, lines 6-10, page 8, lines 18-19 and FIG. 2);

a joint component having a bearing surface (see, e.g., Appellants' specification at page 6, line 22 through page 7, line 1 and FIG. 2);

a mounting element configured for engagement with the joint component and having a spherical articulating portion received within the internal bore of the stem (see, e.g., Appellants' specification at page 7, lines 6-10, and FIG. 2), the spherical articulating portion configured for press-fit engagement with the internal bore such that the spherical articulating portion touches the internal bore around substantially an entire perimeter of the bore defined by the intersection of a plane with the internal bore (see, e.g., Appellants' specification at page 7, lines 6-10, and FIG. 2); and

a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem (see, e.g., Appellants' specification at page 7, lines 20-26, page 8, lines 9-17 and FIG. 2).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 27-35 stand rejected as being anticipated under 35 U.S.C. §102(b) by WO 02/39932 to Horber, an English translation of which is available as U.S. Patent No. 6,818,019 to Horber (hereinafter "Horber").

Claims 27-37 stand rejected as being anticipated under 35 U.S.C. §102(b) by German Patent No. DE 101 23 517 C1 to Glien et al. (hereinafter "Glien").

Claims 32-33 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,228,120 to Leonard et al. (hereinafter "Leonard").

Claims 27-31 and 34-37 stand rejected under 35 U.S.C. §103(a) as being obvious over Leonard in view of Horber and Glien.

(7) ARGUMENT

Claims 27-35 Are Not Anticipated by Horber

Claims 27-35 stand rejected under 35 U.S.C. §102(a) as being anticipated by Horber. (Office Action at page 2). Horber does not teach or disclose each element of the claims. Therefore, the rejections should be overturned.

Discussion re: Patentability of Claim 27

1. <u>Claim 27</u>

Claim 27 recites the following:

A prosthesis comprising:

a stem configured to be implanted within a bone, the stem defining a first coupler bore;

a joint component having a bearing surface and defining a second coupler bore; and

a mounting element having (i) a proximal portion received within the second coupler bore of the joint component in a friction fit manner, and (ii) a spherical articulating portion received within the first coupler bore of the stem,

wherein the stem includes a proximal surface that defines a coupler opening through which the mounting element extends, and the stem, when viewed in a cross-section, further includes an interior wall portion located within the first coupler bore that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line, and

wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line.

Accordingly, claim 27 recites a spherical articulating portion of the mounting element that touches an interior wall portion at a point along a straight line that extends from a proximal surface.

2. Horber Has Been Mischaracterized

The Examiner has alleged that Horber discloses a spherical articulating portion of a mounting element that contacts an interior wall which extends linearly from a ledge to a proximal surface of the stem. (Office Action at pages 2-3). The Examiner has mischaracterized Horber.

Specifically, the Examiner has identified the "interior wall" as either a wall of the bore of disk 31 or a portion of the joint cavity 19. (Office Action at page 3). The Examiner further alleges that the articulation head 25 touches the "internal bore." (Office Action at page 3). Horber states, however, that "a circular edge 23 at the base of the joint cavity 19 forms a bearing for the ball of the joint head 25." (Horber at column 5, lines

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35-38). Contacting the joint cavity 19 at the edge 23 is not the same as contacting a

portion of an interior wall "along a straight line" of that wall.

3. Conclusion

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if

the prior art reference discloses each and every element of the claim. Since Horber does

not disclose a spherical articulating portion of a mounting element that touches an interior

wall which "extends inwardly toward a longitudinal axis of the first coupler bore from the

proximal surface in a straight line" as recited in Appellants' claim 27, Horber does not

anticipate Appellants' claim 27. Accordingly, the Board of Appeals is respectfully

requested to overturn the rejection of claim 27.

Discussion re: Patentability of Claim 28

1. Claim 28

Claim 28 recites the following:

The prosthesis of claim 27, wherein:

the mounting element defines a passageway extending therethough; and

a proximal part of a fastener is located within the passageway, and a distal part of the fastener

contacts the stem.

Accordingly, claim 28 recites a passageway extending through the mounting

element and a fastener within the passageway that contacts the stem.

2. Argument of Claim 27 Applies

As an initial matter, claim 28 depends from claim 27 and includes all of the

limitations of claim 27. The Examiner rejected claim 28 based upon the same prior art

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discussed above with respect to claim 27. Accordingly, for the same reasons set forth above with respect to claim 27, claim 28 is patentable over Horber.

3. A Passageway has not been Alleged

Moreover, claim 28 requires a passageway within the mounting element. The Examiner has failed to allege any such element in the device of Horber. (See Office Action at pages 2-4). It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since the Examiner has failed to identify a "passageway" within the device of Horber, the Examiner has failed to make a *prima facie* rejection of claim 27 as anticipated by Horber. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 28.

4. Horber Does Not Disclose a Fastener as Recited

The Examiner has proposed five different theories for the proposition that the fastener recited in claim 28 is disclosed in Horber. (Office Action at page 3). None of the fasteners, however, are located within a passageway of the mounting element and in contact with the stem.

The first three "interpretations" provided by the Examiner are that the recited fastener is disclosed by the disk 31, a screw 105 or a clamping member 107. (Office Action at page 3). None of these "interpretations" are tenable. Specifically, the disk 31 is not located within a passageway of the head 25 or collar 27. (See Horber at FIG. 1). The screw 105 does not contact the stem. Rather, the screw 105 is positioned within the a slot

101 in a collar 27 which extends away from the stem (see FIG. 2). The clamping member 107 (see FIG. 12) is not located within a passageway of the head 25 or collar 27.

The remaining "interpretations" are not readily discernable as they appear to add components together in some undefined manner. Specifically, one interpretation is "disk 31 + screw 105" and the other is "disk 31 + screw 105 + clamping member 107."

Regardless of the intended meaning, however, the only component that even arguably resides within a "passageway" of the mounting element (head 25 and collar 27) of Horber is the screw 105 and the screw 105 does not contact the stem.

5. Conclusion

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Horber does not disclose each element of the Appellants' claim 28, for any or all of the foregoing reasons, Horber does not anticipate Appellants' claim 28. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 28.

Discussion re: Patentability of Claims 29-31

Claims 29-31 depend from claim 27 and incorporate all the limitations of claim 27. Accordingly, claims 29-31 are patentable over the prior art for at least the same reasons as those set forth above in connection with claim 27 and the Board of Appeals is respectfully requested to overturn the rejection of claims 29-31.

Discussion re: Patentability of Claim 32

Claim 32 recites "a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem." The Examiner rejected claim 32 based upon the same prior art discussed above with respect to claim 28. None of the structures discussed above with respect to the fastener of claim 28 are coupled with *both* the mounting element and the stem, much less include two different portions, one portion coupled with the mounting element and the second portion coupled with the stem. Accordingly, claim 32 is patentable over the prior art for reasons similar to those set forth above in connection with the fastener of claim 28 and the Board of Appeals is respectfully requested to overturn the rejection of claim 32.

Discussion re: Patentability of Claim 33

Claim 33 depends from claim 32 and recites that the "fastener extends within the internal bore of the mounting element." These fastener and internal bore elements, for purposes of this appeal, are the same elements as the passageway and fastener of claim 28. The Examiner rejected claim 33 based upon the same prior art discussed above with respect to claim 28. Accordingly, claim 33 is patentable over the prior art for the same reasons set forth above in connection with the internal passageway and fastener elements of claim 28 as well as the reason set forth above with respect to claim 32 and the Board of Appeals is respectfully requested to overturn the rejection of claim 33.

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Discussion re: Patentability of Claim 34

Claim 34 depends from claim 32 and recites that the "internal bore comprises a tapered portion." Even in the event the slot 101 of Horber (see FIG. 9) is an "internal bore," which it is not, the slot 101 is not tapered. Accordingly, in addition to the reasons set forth with respect to claim 32, claim 34 is patentable over the prior art because Horber fails to disclose a tapered internal bore within the mounting element and the Board of Appeals is respectfully requested to overturn the rejection of claim 34.

Discussion re: Patentability of Claim 35

Claim 35 depends from claim 34 and recites additional limitations. Accordingly, for at least the same reasons set forth with respect to claim 34, claim 35 is patentable over the prior art and the Board of Appeals is respectfully requested to overturn the rejection of claim 35.

Claims 27-37 Are Not Anticipated by Glien

Claims 27-37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Glien. (Office Action at page 3). Glien does not teach or disclose each element of the claims. Therefore, the rejections should be overturned.

Discussion re: Patentability of Claim 27

1. Claim 27

Claim 27 recites, in part, the following:

the stem, when viewed in a cross-section, further includes an interior wall portion located within the first coupler bore that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line, and

wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line.

Accordingly, the wall portion which is contacted by the spherical articulating portion must 1) extend toward the center of the bore from a surface, 2) in a straight line.

2. Glien Has Been Mischaracterized

The Examiner has alleged that Glien discloses the linear wall portion that extends inwardly from a proximal surface in a straight line which is contact by a spherical articulating portion. The Examiner has mischaracterized Glien.

Specifically, the Examiner identifies a portion of the bore of Glien that allegedly discloses the recited limitations at page 6 of the Office Action. The drawing provided by the Examiner is set forth below next to a portion of FIG. 4 of Glien showing the actual location of the component 23.

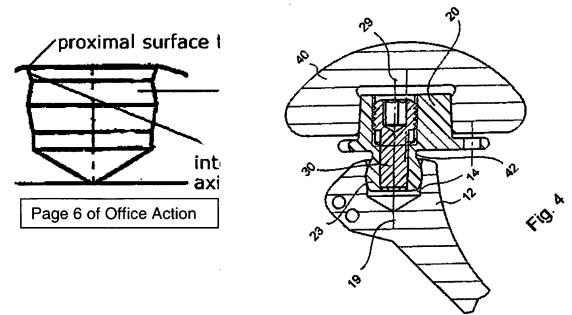


FIG. 4 of Glien clearly shows that the component 23 is *not* contacting the line identified by the Examiner as the straight line extending from the proximal surface of the stem.

Rather, the spherical component 23 contacts the bore of Glien after the wall extending

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from the surface changes direction, flowing outwardly away from the longitudinal axis of

the bore. Therefore, the portion of the wall contacted by the spherical component 23 of

Glien is not the portion which extends "inwardly toward a longitudinal axis of the first

coupler bore from the proximal surface in a straight line" as required by claim 27.

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if

the prior art reference discloses each and every element of the claim. Since Glien does

not disclose a spherical component contacting a portion of a wall that extends "inwardly

toward a longitudinal axis of the first coupler bore from the proximal surface in a straight

line," Glien does not anticipate Appellants' claim 27. Accordingly, the Board of Appeals

is respectfully requested to overturn the rejection of claim 27.

3. Conclusion

For any or all of the above reasons, the Board of Appeals is respectfully requested

to overturn the rejection of claim 27.

Discussion re: Patentability of Claim 28

1. Claim 28

Claim 28 recites the following:

The prosthesis of claim 27, wherein:

the mounting element defines a passageway extending therethough; and

a proximal part of a fastener is located within the passageway, and a distal part of the fastener

contacts the stem.

Accordingly, claim 28 recites a passageway extending through the mounting

element and a fastener within the passageway that contacts the stem.

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2. Argument of Claim 27 Applies

As an initial matter, claim 28 depends from claim 27 and includes all of the limitations of claim 27. The Examiner rejected claim 28 based upon the same prior art discussed above with respect to claim 27. Accordingly, for the same reasons set forth above with respect to claim 27, claim 28 is patentable over Glien.

3. Glien Does Not Disclose a Fastener as Recited

The Examiner has alleged that the cylindrical rod 31 of Glien discloses a fastener as recited in claim 28. (Office Action at page 6). The Examiner has failed to identify a fastener including all of the limitations recited in claim 28.

Specifically, cylindrical rod 31 does not contact the stem 12 of Glien. While the Examiner opines that the words "for engagement" are functional, the claim recites that the fastener "contacts" the stem. The word "contacts" is not functional. None of the figures of Glien show the cylindrical rod 31 in contact with the stem 12. Moreover, the configuration of the device of Glien appears to make such contact impossible. (See, e.g., FIG. 4 above).

4. Conclusion

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Glien does not disclose each element of the Appellants' claim 28, for any or all of the foregoing reasons, Glien does not anticipate Appellants' claim 28. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 28.

Discussion re: Patentability of Claims 29-31

Claims 29-31 depend from claim 27 and incorporate all the limitations of claim 27. Accordingly, claims 29-31 are patentable over the prior art for at least the same reasons as those set forth above in connection with claim 27 and the Board of Appeals is respectfully requested to overturn the rejection of claims 29-31.

Discussion re: Patentability of Claim 32

Claim 32 recites "a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem." The Examiner rejected claim 32 based upon the same prior art discussed above with respect to claim 28. As discussed above, the cylindrical rod 31 is not even in contact with the stem 12, much less "coupled" with the stem. Accordingly, claim 32 is patentable over the prior art for reasons similar to those set forth above in connection with the fastener of claim 28 and the Board of Appeals is respectfully requested to overturn the rejection of claim 32.

Discussion re: Patentability of Claim 33

Claim 33 depends from claim 32 and recites that the "fastener extends within the internal bore of the mounting element." These fastener and internal bore elements, in combination with the coupling limitation of claim 32, are the same elements for purposes of this appeal as the passageway and fastener elements of claim 28. The Examiner rejected claim 33 based upon the same prior art discussed above with respect to claim 28.

Accordingly, claim 33 is patentable over the prior art for the same reasons set forth above in connection with the internal passageway and fastener of claim 28 as well as the reason set forth with respect to claim 32 and the Board of Appeals is respectfully requested to overturn the rejection of claim 33.

Discussion re: Patentability of Claim 34

Claim 34 depends from claim 32 and recites that the "internal bore comprises a tapered portion." Neither the bore 24 nor the bore 25 of Glien are tapered. (See, e.g., FIG. 3). Accordingly, in addition to the reasons set forth with respect to claim 32, claim 34 is patentable over the prior art because Glien fails to disclose a tapered internal bore within the mounting element and the Board of Appeals is respectfully requested to overturn the rejection of claim 34.

Discussion re: Patentability of Claim 35

Claim 35 depends from claim 34 and recites additional limitations. Accordingly, for at least the same reasons set forth with respect to claim 34, claim 35 is patentable over the prior art and the Board of Appeals is respectfully requested to overturn the rejection of claim 35.

Claims 32-33 Are Not Anticipated by Leonard

Claims 32-33 stand rejected under 35 U.S.C. §102(b) as being anticipated by Leonard. (Office Action at page 3). Leonard does not teach or disclose each element of the claims. Therefore, the rejections should be overturned.

Discussion re: Patentability of Claim 32

1. Claim 32

Claim 32 recites:

A prosthesis comprising:

a stem configured to be implanted within a bone, the stem including an internal bore:

a joint component having a bearing surface;

a mounting element configured for engagement with the joint component and having a spherical articulating portion received within the internal bore of the stem, the spherical articulating portion configured for press-fit engagement with the internal bore such that the spherical articulating portion touches the internal bore around substantially an entire perimeter of the bore defined by the intersection of a plane with the internal bore; and

a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem.

Accordingly, the mounting element is configured for "press-fit" engagement with the stem.

2. "Press-Fit" is Not Functional

The Examiner has apparently failed to consider the specific configuration recited in claim 32 under the pretense that the configuration is merely "functional." The term "press-fit" is a structural limitation, not merely a potential use.

Specifically, Wikipedia states:

An interference fit (sometimes called a press fit) is a fastening between two parts which is achieved by friction after the parts are pushed together, rather than by any other means of fastening. For metal parts in particular, the friction that holds the parts together is often greatly increased by compression of one part against the other, which relies on the tensile and compressive strengths of the materials the parts are made from. Typical examples of interference fits are the press fitting of shafts into bearings or bearings into their housings and the attachment of watertight connectors to cables. An interference fit also results when pipe fittings are assembled and tightened...

An interference fit is generally achieved by shaping the two mating parts so that one or the other (or both) slightly deviate in size from the nominal dimension. The word interference refers to the fact that one part slightly interferes with the space that the other is taking up. For example: A shaft may be ground slightly oversize, and the hole in the bearing (through which it is going to pass with an interference fit) may be ground slightly undersize. When the shaft is pressed into the bearing, the two parts interfere with each other's occupation of space; the result is that they plastically deform slightly, each being compressed, and the interface between them is one of extremely high friction—so high that even large amounts of torque cannot turn one of them relative to the other; they are locked together and they turn in unison.

http://en.wikipedia.org/wiki/Interference_fit

Thus, the term "press-fit" introduces a specific structural relationship between the mounting element and the stem.

3. Leonard's Device is Not "Press-Fit"

The Examiner has alleged that the structural relationship set forth in claim 32 is disclosed by Leonard at column 6, lines 25-31. (Office Action at page 7). The Examiner has mischaracterized Leonard.

Specifically, at column 6, lines 24-26 Leonard discloses that the ball joint 10 is "designed to fit the hemispherical bearing formed by the cavity 7." Leonard further notes that the external wall 10a of the ball joint has a radius "of the same radius as said cavity 7, plus tolerance." (Leonard at column 6, lines 27-28). Thus, Leonard discloses designing the radius of the ball joint 10 to *not interfere with the cavity*. The absence of an interference fit allows the ball joint to rotate within the hemispherical cavity. (See, e.g., Leonard at column 8, lines 57-60).

Additionally, Leonard states that "humeral rod and humeral plate have hemispherical contact bearings and are designed and arranged so that the ball joints of the

humeral plate and the locking unit can oscillate in all directions around a point 0 representing the center of the hemispherical cavity in the humeral rod." (Leonard at column 3, lines 16-20). A fit which allows oscillation is not the same as a fit whereby one component is frictionally held by another component.

Additionally, any possibility that Leonard intended to use the foregoing description of tolerances as a way to describe a press-fit is contraindicated by Leonard. Specifically, Leonard appears to use the term "force-fit" to describe a "press-fit". (See, e.g., Leonard at column 7, lines 48-50).

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Because the term "press-fit" is a structural limitation and because Leonard does not disclose a spherical component that is press-fit into the stem as required by claim 32, Leonard does not anticipate Appellants' claim 32. Accordingly, the Board of Appeals is respectfully requested to overturn the rejection of claim 32.

4. <u>Conclusion</u>

For any or all of the above reasons, the Board of Appeals is respectfully requested to overturn the rejection of claim 32.

Discussion re: Patentability of Claim 33

Claim 33 depends from claim 32 and incorporates all the limitations of claim 32.

Accordingly, claim 33 is patentable over the prior art for at least the same reasons as

those set forth above in connection with claim 32 and the Board of Appeals is respectfully requested to overturn the rejection of claim 32.

Claims 27-31 and 34-37 Are Not Obvious

Claims 27-31 and 34-37 stand rejected under 35 U.S.C. §103(a) as being obvious over Leonard in view of Horber and Glien. There is no motivation for the proposed combination. Moreover, the proposed combination fails to arrive at the invention recited in claims 27-31 and 34-37. Therefore, the rejections should be overturned.

Discussion Re: Patentability of Claim 27

1. Claim 27

Claim 27 recites:

A prosthesis comprising:

a stem configured to be implanted within a bone, the stem defining a first coupler

bore;

a joint component having a bearing surface and defining a second coupler bore;

and

a mounting element having (i) a proximal portion received within the second coupler bore of the joint component in a friction fit manner, and (ii) a spherical articulating portion received within the first coupler bore of the stem,

wherein the stem includes a proximal surface that defines a coupler opening through which the mounting element extends, and the stem, when viewed in a cross-section, further includes an interior wall portion located within the first coupler bore that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line, and

wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line.

Claim 27 thus requires a spherical articulating portion of a mounting element to be fastened to the stem by friction after the parts are pushed together. Additionally, the contact occurs along an interior wall portion that extends inwardly toward a longitudinal axis of the first coupler bore from a proximal surface of the stem in a straight line

2. <u>Leonard Does Not Disclose a Spherical Press-fit Component</u>

i) >

The Examiner has rejected claim 27 primarily based upon Leonard with further reference to Horber and Glien for the interior wall portion. (Office Action at pages 12-13). The proposed modification fails to arrive at the invention of claim 27.

Specifically, claim 27 recites that the spherical articulating portion of a mounting element is friction-fit to the stem which, for purposes of this Appeal, is the same as "press-fit". The Examiner has made the same "functional" argument and cited to the same art for the "friction-fit" limitation of claim 27 that was discussed above with respect to claim 32. (See, e.g., Office Action at page 13).

Therefore, for the same reasons set forth above with respect to claim 32, Leonard does not describe a spherical articulating portion of a mounting element that is fastened to the stem by friction after the parts are pushed together. Accordingly, even if Leonard is modified in the manner proposed by the Examiner, the modification fails to arrive at the invention recited in claim 27. Accordingly, under MPEP § 2143.03, claim 27 is patentable over the prior art.

3. Glien Has Been Mischaracterized

Moreover, the shortcomings of Glien with respect to the recited interior wall portion were discussed above with respect to the rejection of claims 27-37. Therefore, as discussed above, Glien does not disclose an interior wall portion as recited in claim 27.

Accordingly, even if Leonard is modified in the manner proposed by the Examiner, the

modification fails to arrive at the invention recited in claim 27. Accordingly, under MPEP § 2143.03, claim 27 is patentable over the prior art.

4. There is No Motivation for the Proposed Modification

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The Examiner has proposed that the device of Leonard be modified "in order to permit movement of the articulating surface of a mounting element/articulation body in multiple degrees of freedom." The proposed motivation is not convincing.

MPEP 2144 notes that "[t]he strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination." Citing, In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

Leonard, however, already provides the result proposed by the Examiner. Specifically, the stated object of Leonard is to "provide a shoulder prosthesis that permits continuous independent adjustments of the medial offset and the posterior offset". (Leonard at column 2, lines 30-32). To this end, Leonard provides a device which allows four elementary rotations. (Leonard at column 8, line 61 through column 9, line 14). Thus, Leonard provides the various rotations to achieve continuous independent adjustments of the medial offset and the posterior offset.

Therefore, while motivation to combine references may be found in an advantage arising from the combination, there can be no advantage from the proposed combination when the alleged advantage is already present in the system which the Examiner proposes

to modify. Accordingly, the Examiner has failed to identify a legally cognizable motivation for the proposed modification of Leonard.

Because there is no suggestion or motivation for the proposed combination, a prima facie case of obviousness has not been made and the rejection of claim 27 under 35 U.S.C. § 103(a) should be overturned.

5. Conclusion

For any or all of the foregoing reasons, it is respectfully submitted that claim 27 is patentable over Leonard in view of Horber and Glien, and the Board of Appeals is respectfully requested to overturn the rejection of claim 27.

Discussion Re: Patentability of Claims 28-31

Claims 28-31 were rejected based upon the same combination discussed above with respect to claim 26. Each of claims 28-31 depend, either directly or by way of one or more intermediate claims, from claim 27 and include all of the limitations of claim 27. Therefore, for at least the reasons set forth above with respect to claim 27, claims 28-31 are patentable.

Discussion re: Patentability of Claim 34

Claim 34 depends from claim 32 and includes all of the limitations of claim 32. Claim 34 was rejected based, apparently, upon Leonard for the limitations of claim 32 with further reference to Horber and Glien for the limitations added by claim 34. (See, e.g., Office Action at page 12). As discussed above, Leonard fails to disclose all of the

limitations of claim 32. Therefore, even if Leonard is modified in the manner proposed by the Examiner, such modification fails to arrive at the invention of claim 34.

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Additionally, the proposed motivation for the modification of the prior art with respect to claim 34 is the same motivation discussed above with respect to claim 27. Therefore, for at least the reasons set forth above with respect to claim 27, there is no motivation for the proposed modification of Leonard and a *prima facie* case of obviousness has not been made.

Additionally, claim 34 recites "wherein the internal bore comprises a tapered portion." This limitation to the "internal bore of claim 32 results in press-fit that is achieved using a taper. The Examiner has apparently relied upon either Glien or Leonard for disclosing a press-fit that uses a taper, although the Office Action is not clear on this point. Regardless, neither the bore 24 nor the bore 25 of Glien are tapered. (See, e.g., FIG. 3). Moreover, the device of Leonard does not disclose a press-fit as discussed above with respect to claim 27. Accordingly, the art cited by the Examiner fails to disclose the "tapered" limitation of claim 34 and claim 34 is patentable over the art cited by the Examiner.

For any or all of the foregoing reasons, it is respectfully submitted that claim 34 is not obvious over Leonard in view of Horber and Glien, and the Board of Appeals is respectfully requested to overturn the rejection of claim 34.

Discussion Re: Patentability of Claims 35-37

Claims 35-37 were rejected based upon the same combination discussed above with respect to claim 34. Each of claims 35-37 depend, either directly or by way of one

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or more intermediate claims, from claim 34 and include all of the limitations of claim 34 and additional limitations. Therefore, for at least the reasons set forth above with respect to claim 34, claims 35-37 are patentable.

CONCLUSION

Claims 27-35 are not anticipated by Horber, claims 27-37 are not anticipated by Glien, and claims 32-33 are not anticipated by Leonard. Additionally, claims 27-31 and 34-37 are not obvious over Leonard in view of Horber and Glien. Accordingly, the Board of Appeals is respectfully requested to reverse the rejections of claims 27-37.

Respectfully submitted,

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(8) CLAIMS APPENDIX

Claim 27. A prosthesis comprising:

a stem configured to be implanted within a bone, the stem defining a first coupler bore;

a joint component having a bearing surface and defining a second coupler bore; and

a mounting element having (i) a proximal portion received within the second coupler bore of the joint component in a friction fit manner, and (ii) a spherical articulating portion received within the first coupler bore of the stem,

wherein the stem includes a proximal surface that defines a coupler opening through which the mounting element extends, and the stem, when viewed in a cross-section, further includes an interior wall portion located within the first coupler bore that extends inwardly toward a longitudinal axis of the first coupler bore from the proximal surface in a straight line, and

wherein the spherical articulating portion of the mounting element touches the interior wall portion at a point along the straight line.

Claim 28. The prosthesis of claim 27, wherein:

the mounting element defines a passageway extending therethough; and a proximal part of a fastener is located within the passageway, and a distal part of the fastener contacts the stem.

Claim 29. The prosthesis of claim 27, wherein the second coupler bore of the joint component defines a female taper component, and the proximal portion of the mounting element defines a male taper component configured to mate with the female taper component.

Claim 30. The prosthesis of claim 27, wherein the stem is configured to be implanted within a humerus.

Claim 31. The prosthesis of claim 27, wherein the bearing surface of the joint component is configured to mate with a glenoid component.

Claim 32. A prosthesis comprising:

a stem configured to be implanted within a bone, the stem including an internal bore;

a joint component having a bearing surface;

a mounting element configured for engagement with the joint component and having a spherical articulating portion received within the internal bore of the stem, the spherical articulating portion configured for press-fit engagement with the internal bore such that the spherical articulating portion touches the internal bore around substantially an entire perimeter of the bore defined by the intersection of a plane with the internal bore; and

a fastener having a first portion coupled with the spherical articulating portion of the mounting element and a second portion coupled with the stem. Claim 33. The prosthesis of claim 32, wherein the mounting element comprises an internal bore and the fastener extends within the internal bore of the mounting element.

Claim 34. The prosthesis of claim 32, wherein the internal bore comprises a tapered portion, and the perimeter of the bore is defined by the intersection of the plane with the tapered portion of the bore.

Claim 35. The prosthesis of claim 34, wherein the tapered portion extends from an external surface portion of the stem.

Claim 36. The prosthesis of claim 35, wherein the internal bore further comprises a threaded portion and the fastener is threadingly engaged with the threaded portion of the internal bore.

Claim 37. The prosthesis of claim 36, wherein the mounting element further comprises a bearing portion within a cavity and the fastener is configured to bear upon the bearing portion.

(9) EVIDENCE APPENDIX

None.

(10) RELATED PROCEEDINGS APPENDIX

None.